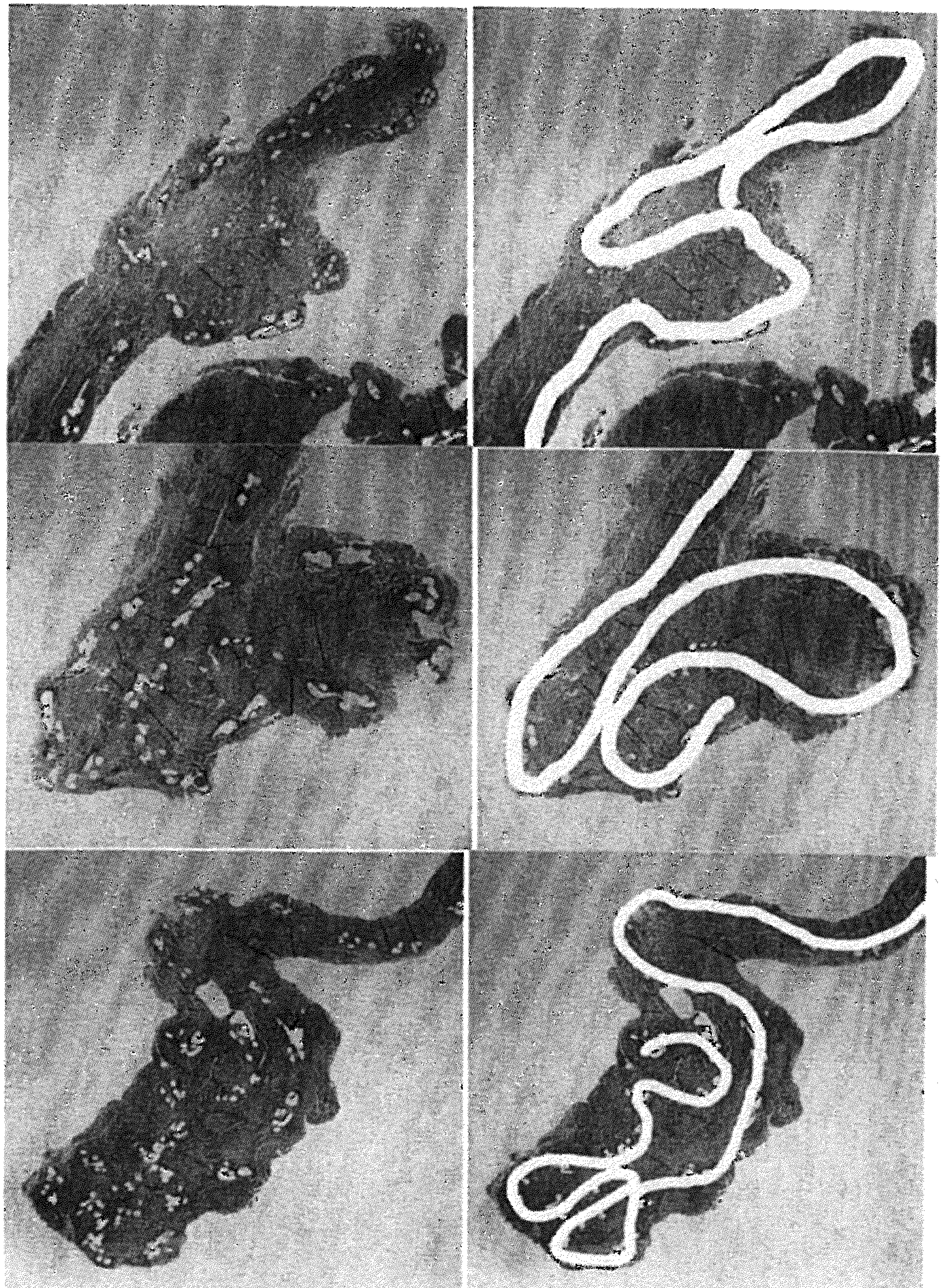


Figure 14. Several examples of mesh deformation.

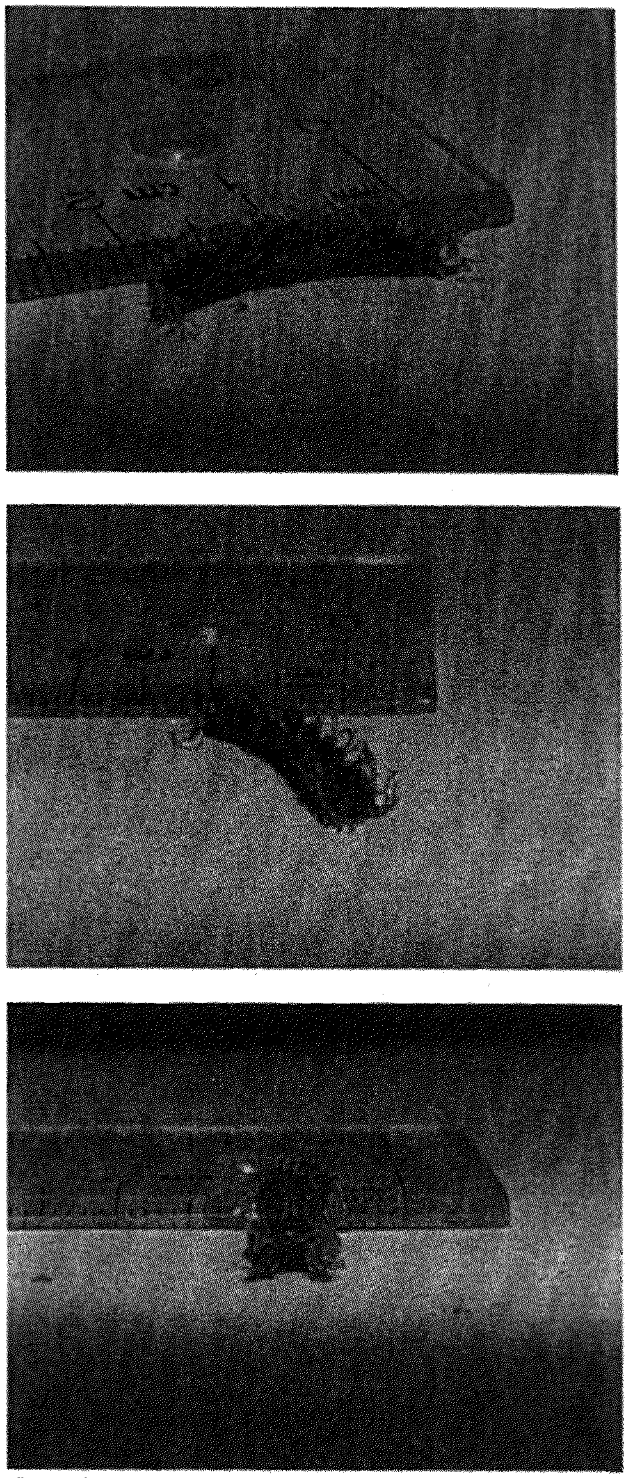
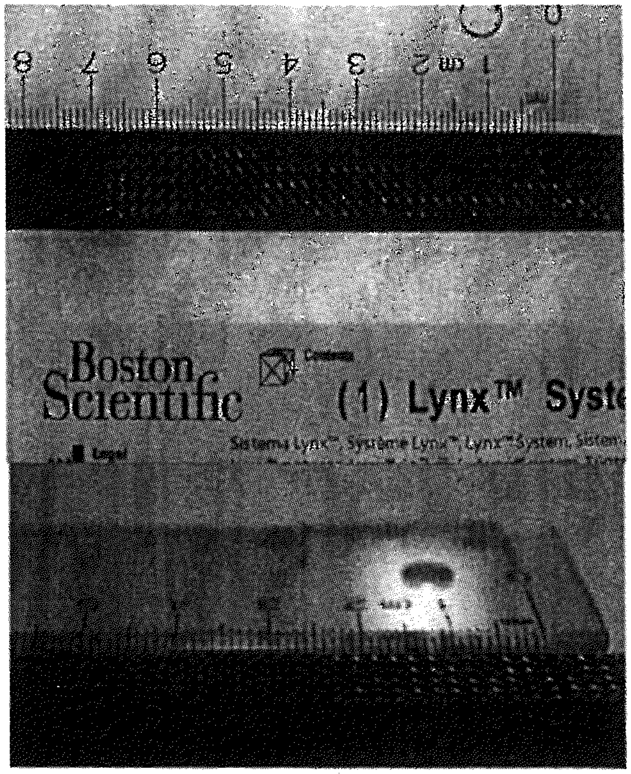
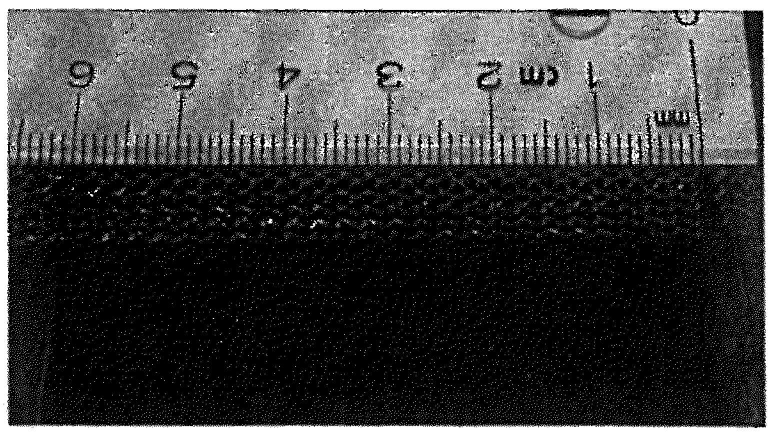


Figure 15. A different brand of transobturator mesh explanted with minimal tissue
Note similar curling of the edges and bowing along the long axis.


Boston Scientific
(1) Lynx™



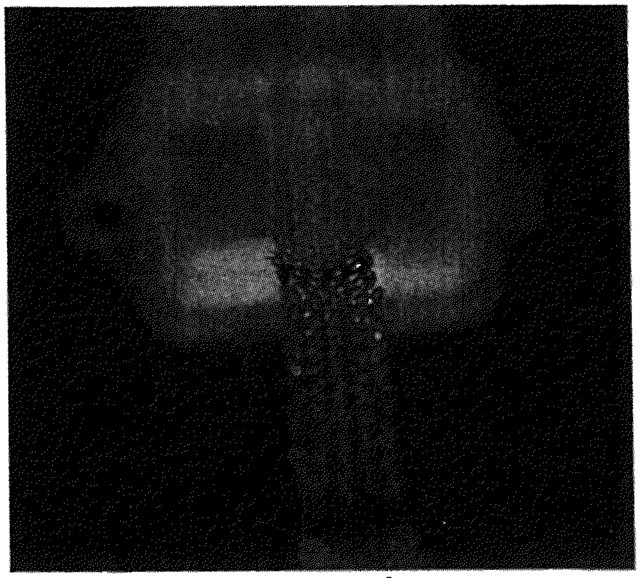
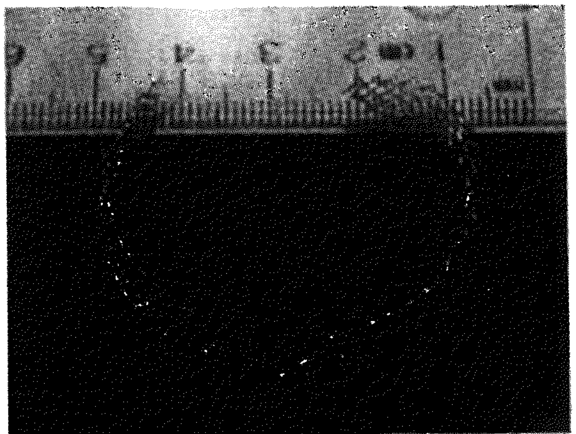
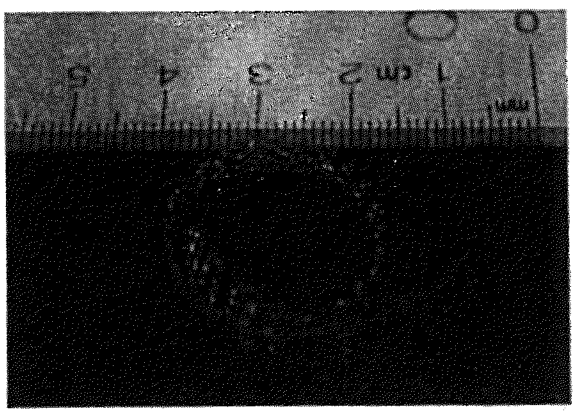


Figure 16a. Boston scientific transobturator tape, stretch test
The tape has been stretched 20% of its original length. Note raised edges during stretching at the lower panel.





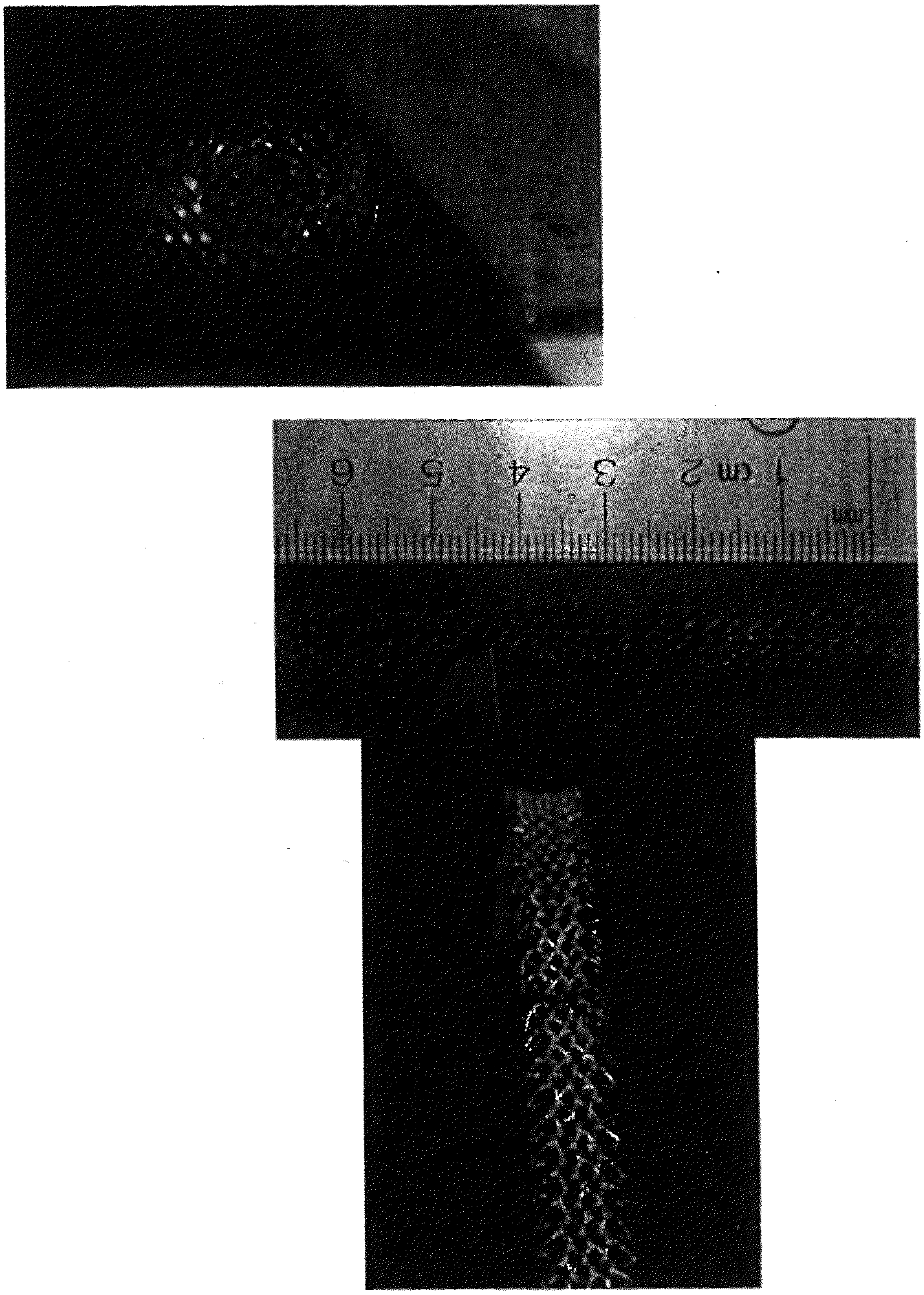


Figure 16b. Configuration after stretch tests

Configuration after 30 second single stretching at the top row; and repetitive stretching during 30 seconds on the lower panels. The mesh acquires permanent lengthening, narrowing and curling deformation.

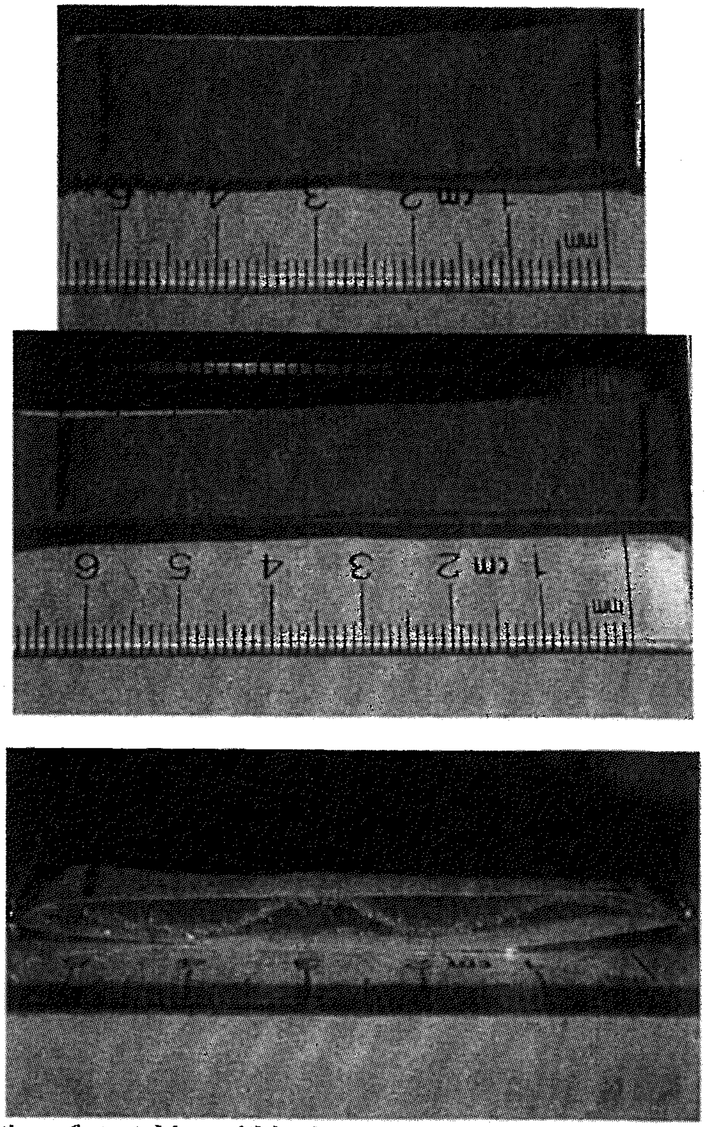
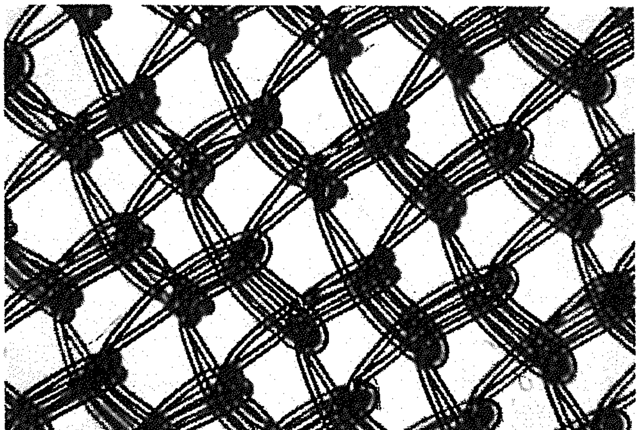
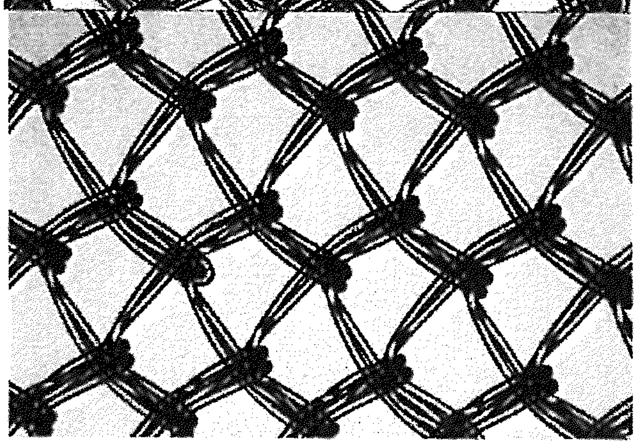
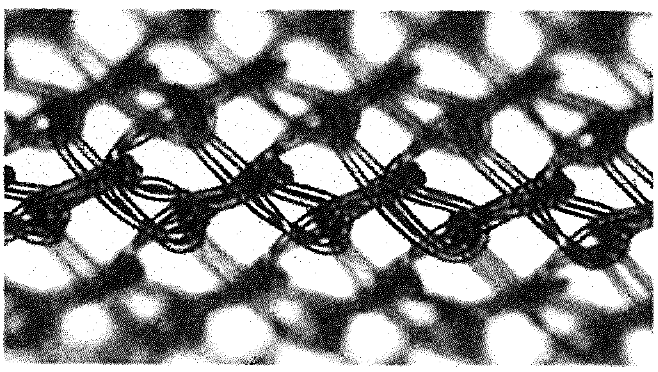


Figure 17. Simulation of stretching within tissue

The sling is sandwiched between latex elastic tape. The elastic tape returns to the original length after stretching similarly to human tissue. The mesh sling is permanently lengthened after stretching, which forces it into deformation. Note similarity to the examples of explanted meshes in Figure 11.







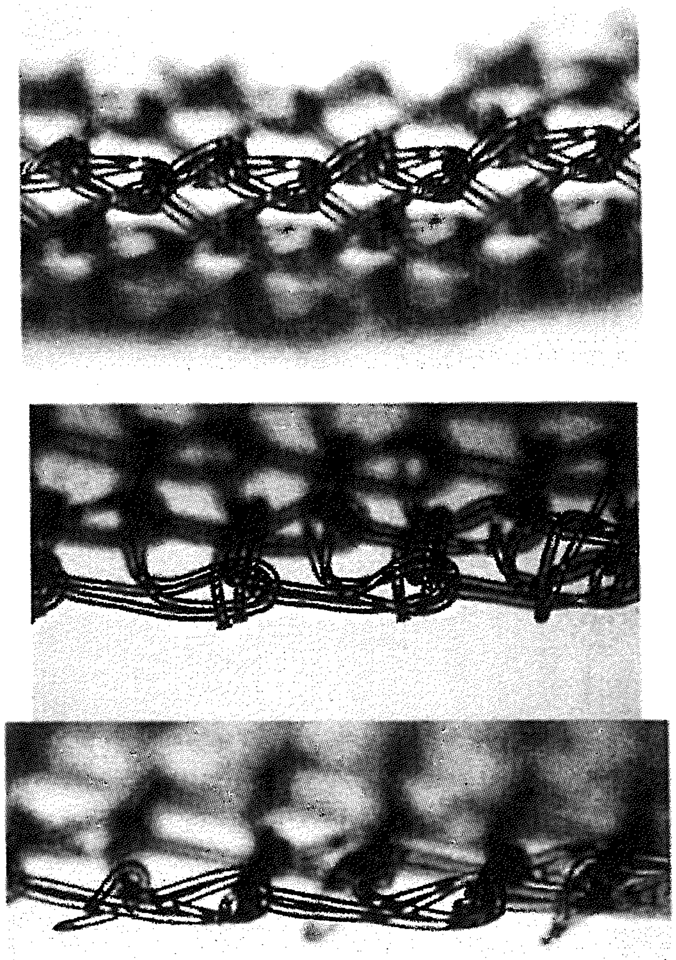
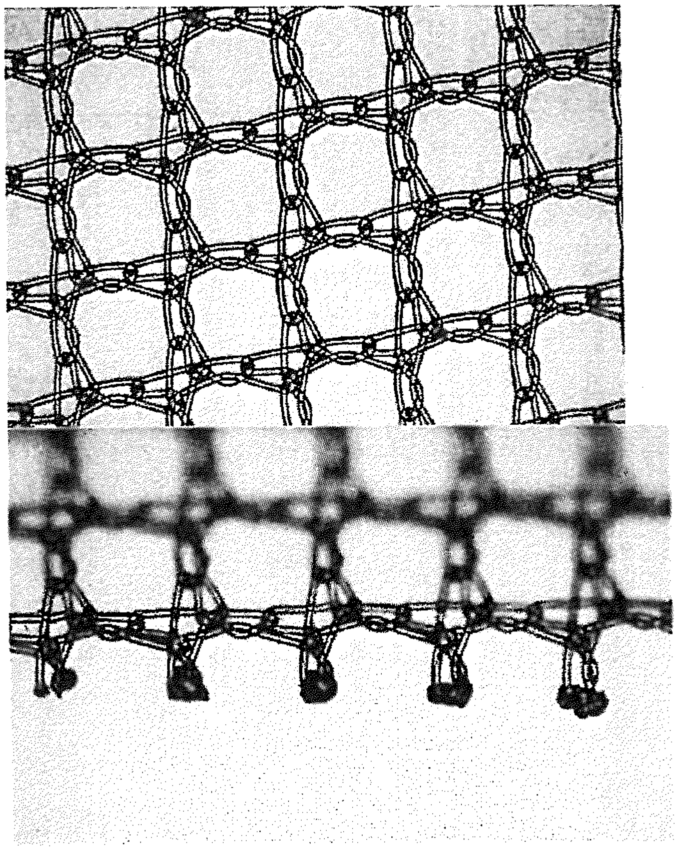
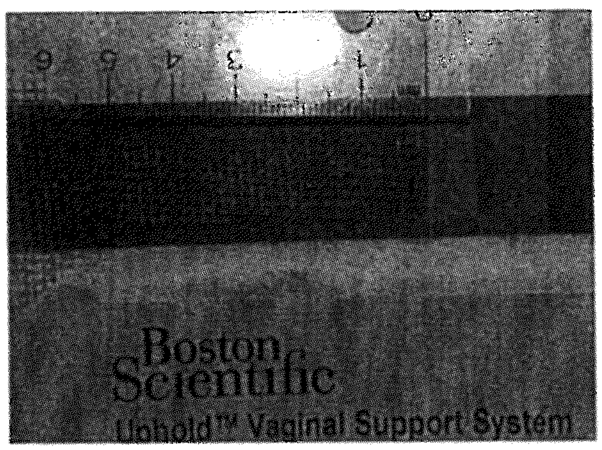


Figure 18. New transobturator slings, Boston Scientific on the right, a different brand on the left

The mesh is knitted with the loops in one direction (loop ends point to the right in the pictures). The loops bow towards one surface of the mesh (upward in the pictures).




Boston
Scientific
Uphold™ Vaginal Support System

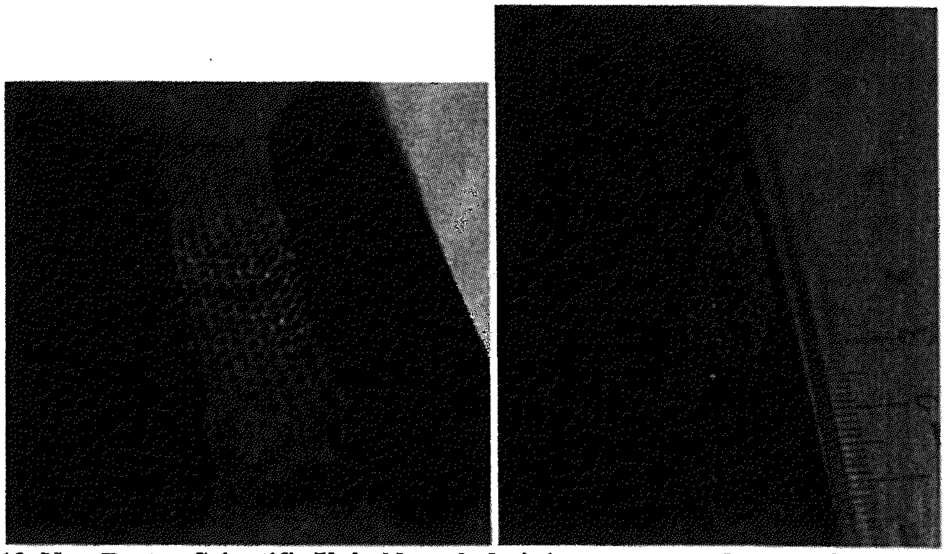


Figure 19. New Boston Scientific Uphold mesh, knitting pattern and a stretch test
The mesh has a different knitting pattern and has been heat treated. Note the different, spiraling pattern of deformation occurring after stretching.

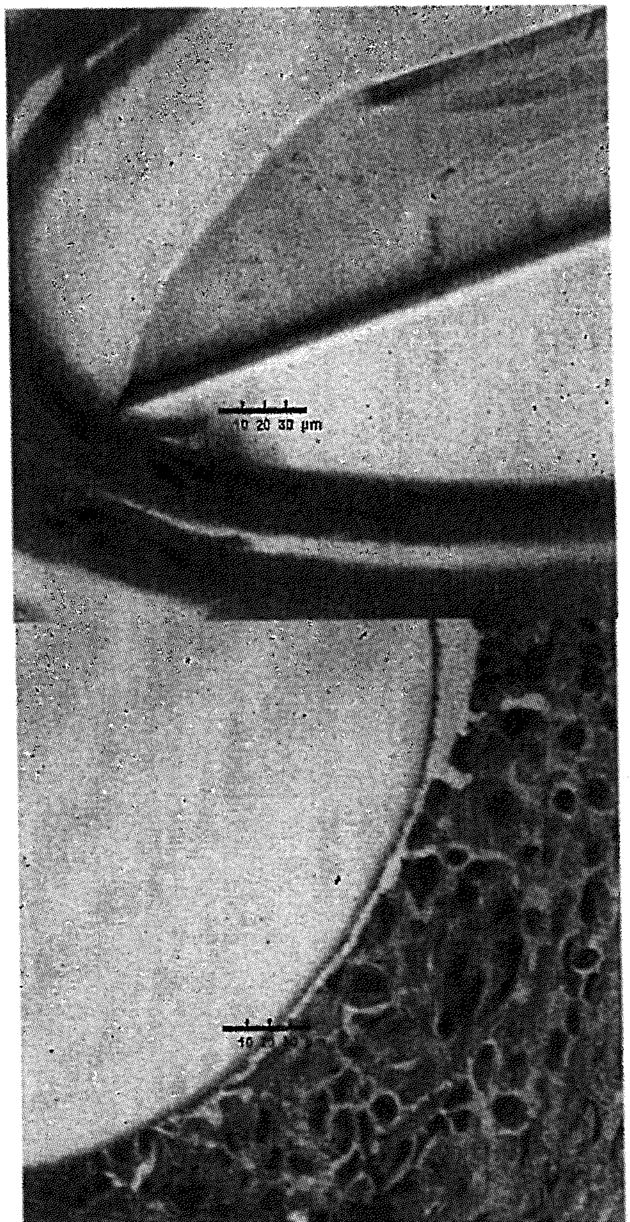


Figure 20a. Meshes explanted after 9 years (left) and 1 year (right)

Transobturator slings of other brand explanted 9 (left) and 1(right) year after placement in the body. There is an outer layer of material absorbing dye. This layer is thicker in the left mesh.

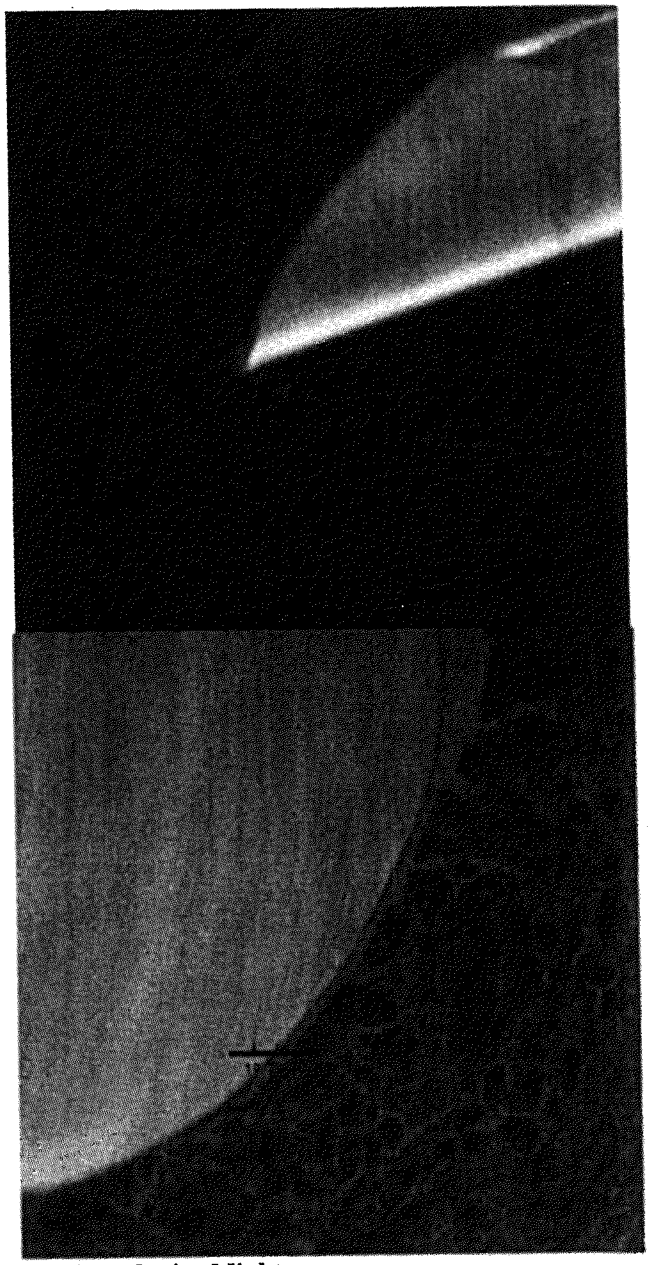


Figure 20b. Examination in polarized light.

The light in the microscope is polarized. When two polarizing filters, below and above specimen are in perpendicular orientation to each other the light is fully blocked. However, if there is an object with polarizing optical properties between the filters, it changes the light orientation and becomes visible.

The scale is placed at approximately the same curvature radius to avoid possible difference of section angle. The outer layer has the same polarizing properites as the non-staining polypropylene core. This layer of degraded polypropylene resembles a tree bark. It is adherent to the tissue and/or the glass slide, while the central core detaches from the "bark" and the glass slide surface.

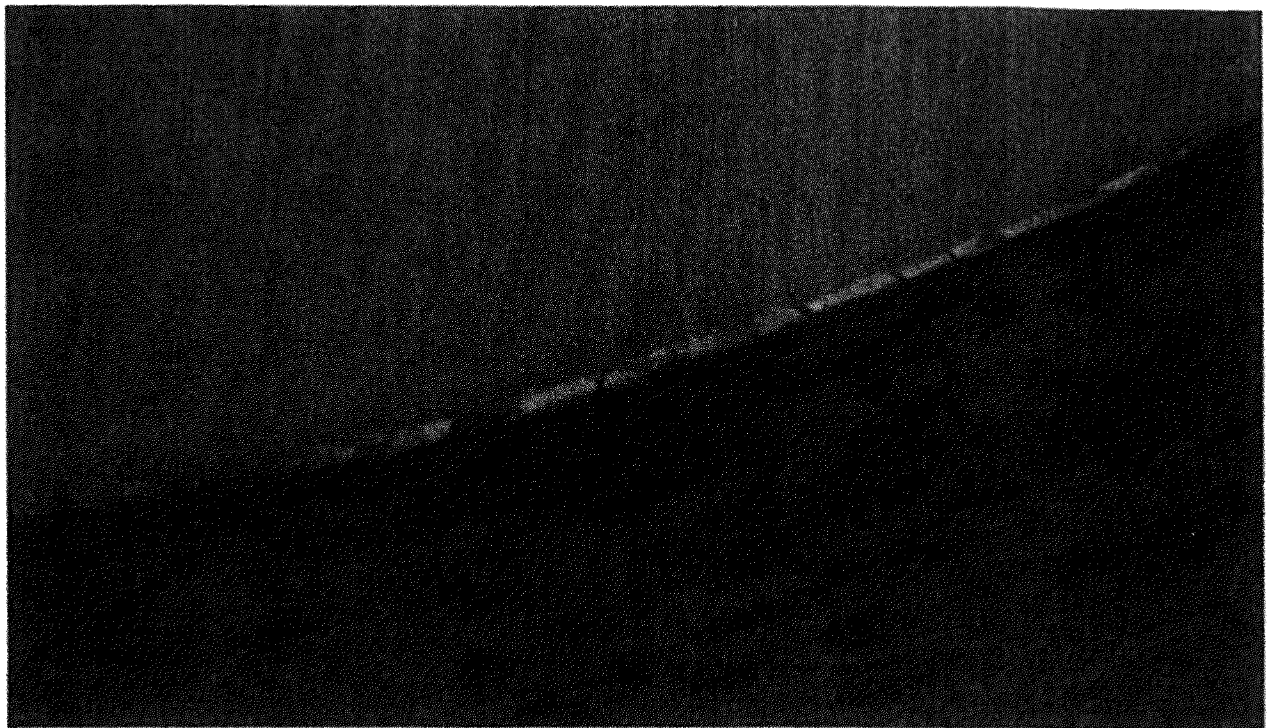


Figure 21. Boston Scientific Pinnacle/Uphold type of mesh, cracking of the "bark".
Note the more brittle nature of the bark.

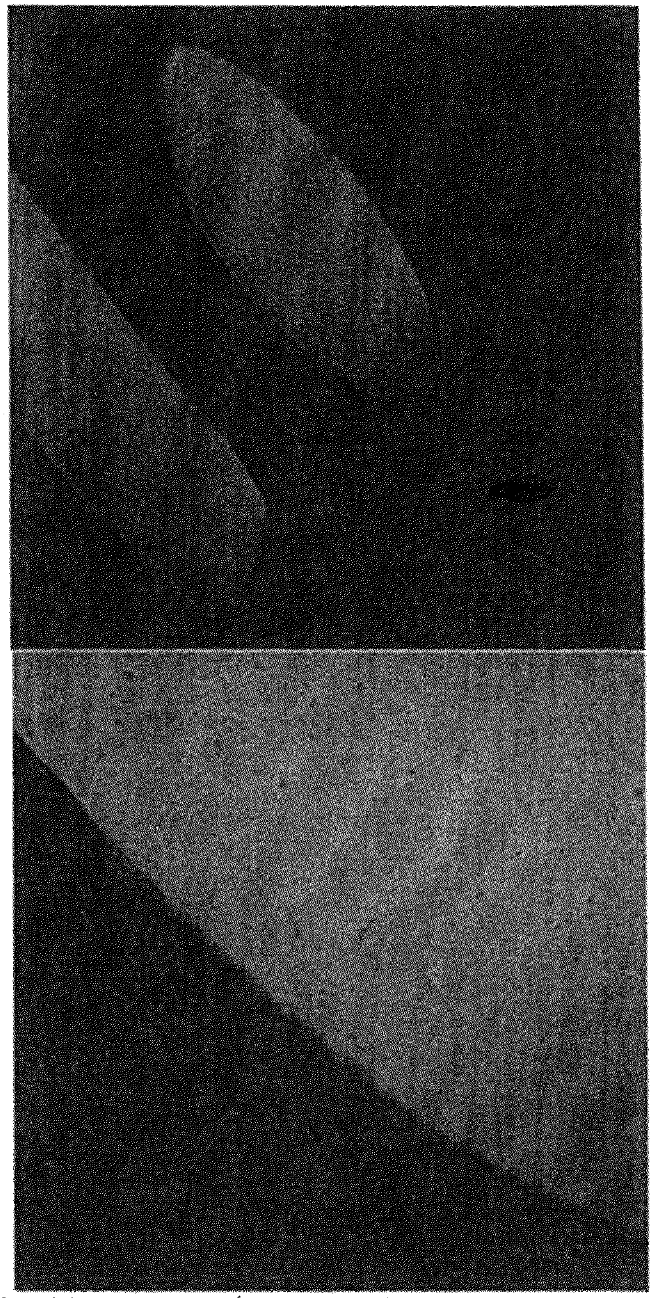


Figure 22. New mesh subjected to the same processing
The mesh has been subjected to the same formalin fixation, chemical processing, paraffin embedding and staining procedures. Note the absence of staining outer layer.

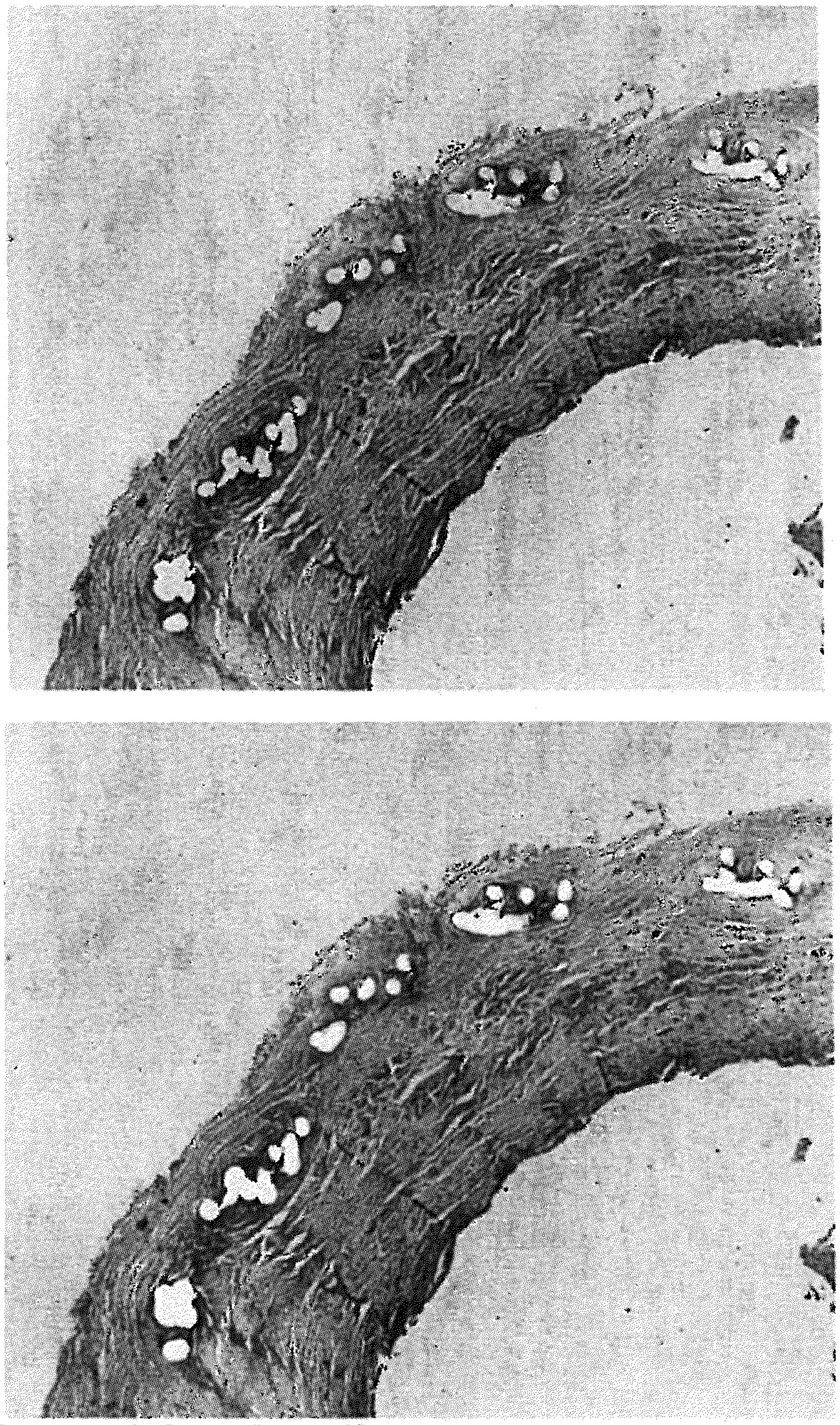


Figure 23. Immunostain for myeloperoxidase.

Myeloperoxidase is an oxidative enzyme used by inflammatory cells. The staining is denser in the areas surrounding the mesh structure indicating that the mesh is in an oxidative environment.

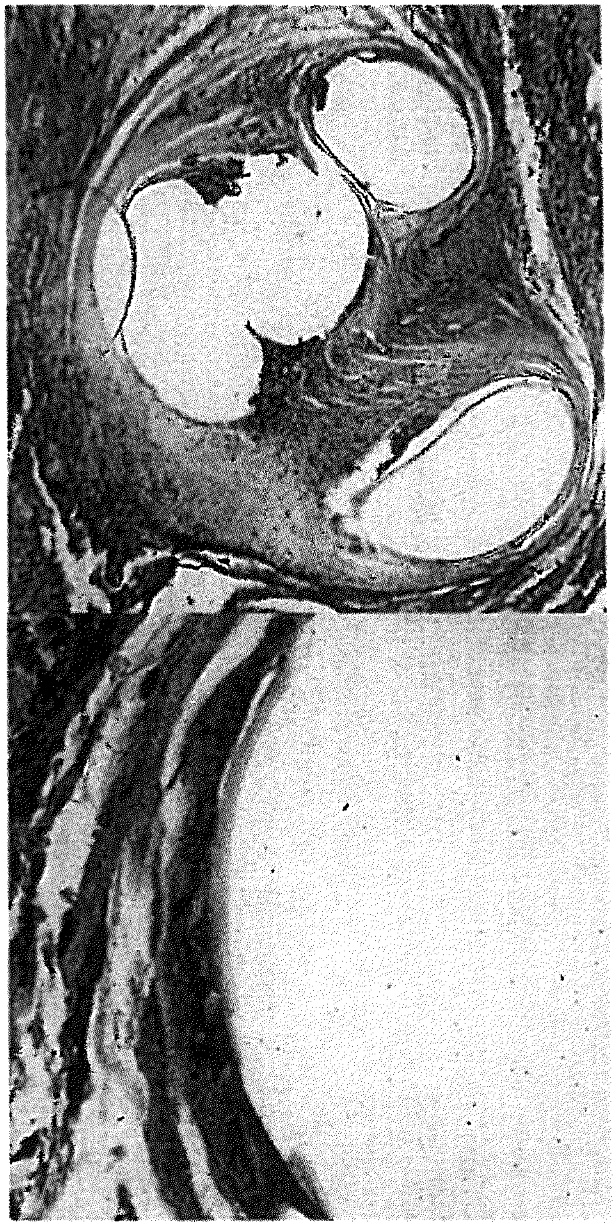


Figure 24. Myeloperoxidase stain

The enzyme is present in the tissue, but is not present in the "bark" (right), which additionally proves that the "bark" is not deriving from human tissue.

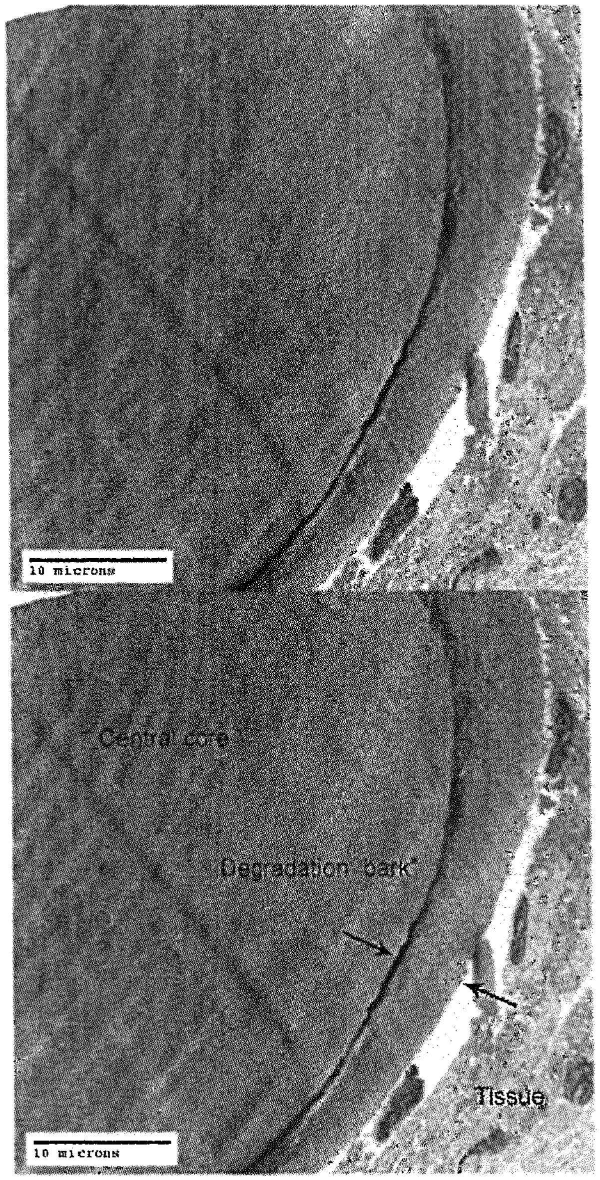


Figure 25a. Transmission electron microscopy (TEM).

This type of EM is similar to conventional light microscopy, except an electron beam is used to see the structures at ultra high magnification while a conventional microscopy uses light to shine through thin cross sections.

A mesh filament with a layer of altered polypropylene at the surface. The thickness is about 4 microns

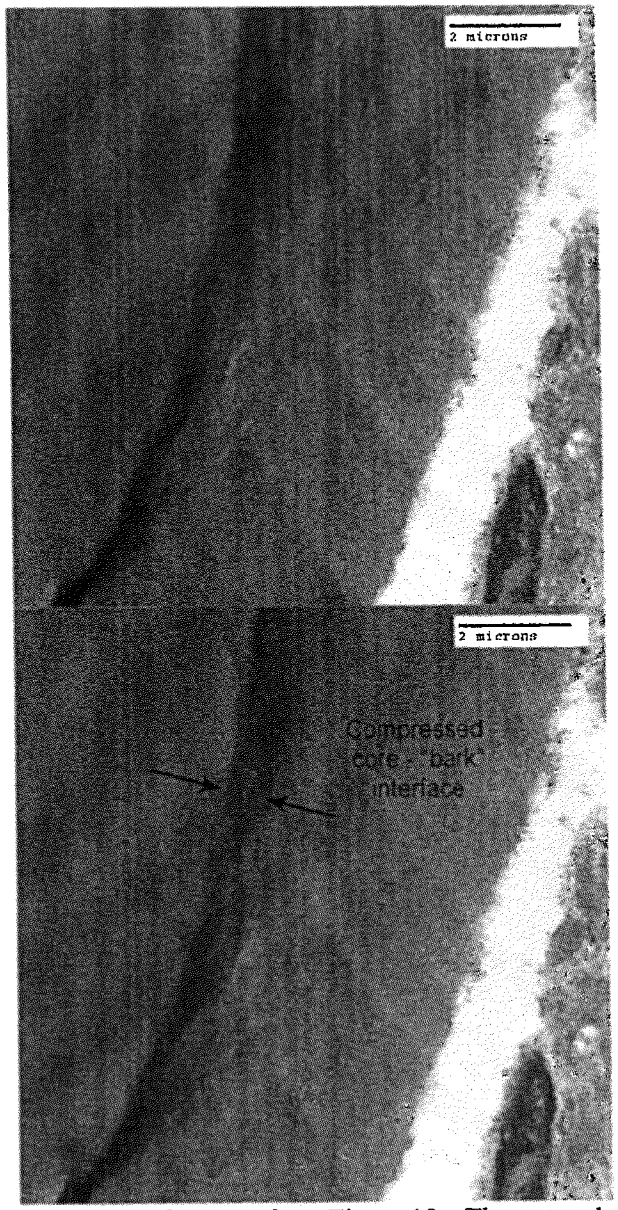


Figure 25b. Higher magnification of an area from Figure 18a. The outer altered "bark" is separated from the central core, where the interface is compressed and disrupted. This disruption explains the separation of the outer "bark" from the core.

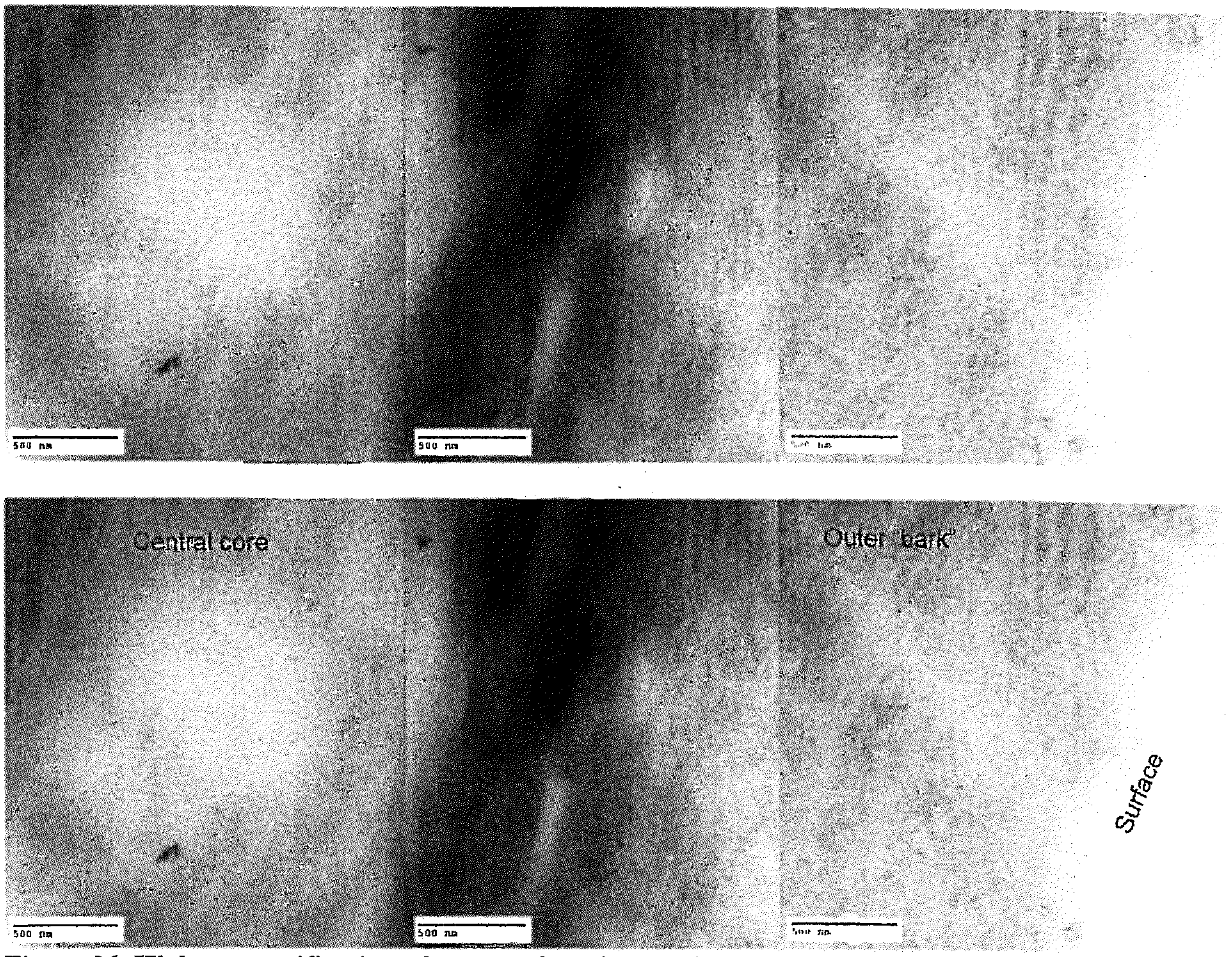


Figure 26. Higher magnification of an area from Figure 18. Lower panel is a labeled copy. Three images, taken in linear sequence, are combined to show the ultrastructural difference between the outer layer and the central core. Note the difference in grain size.

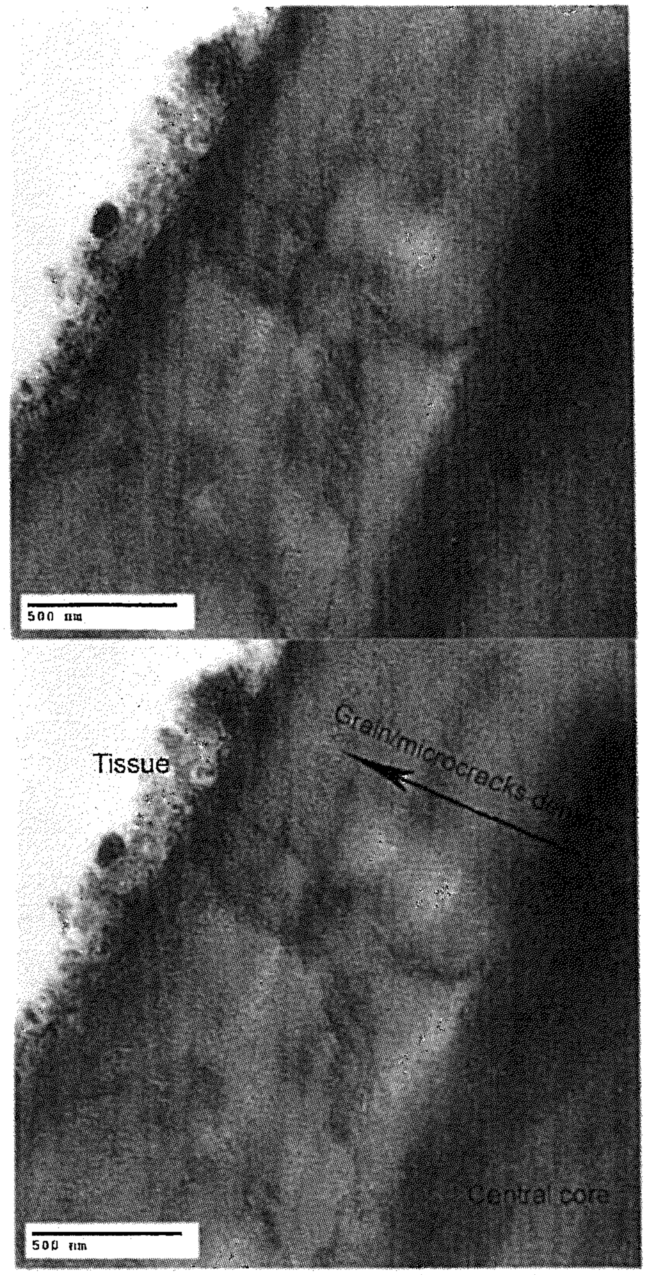
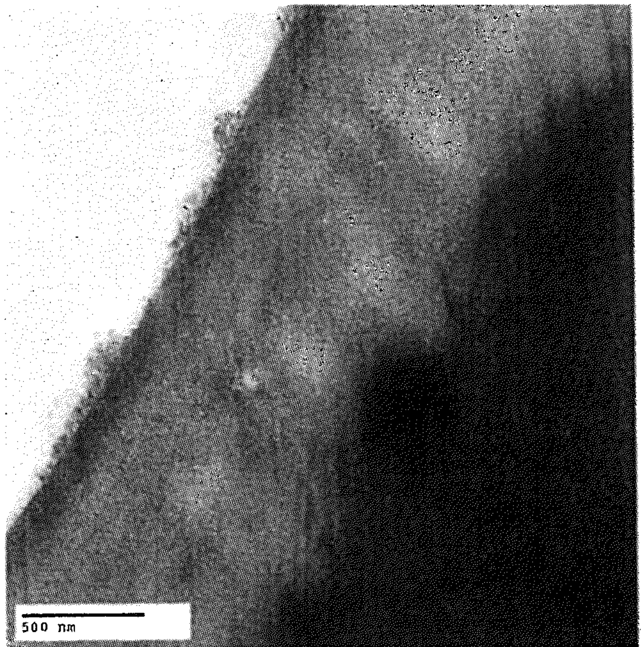
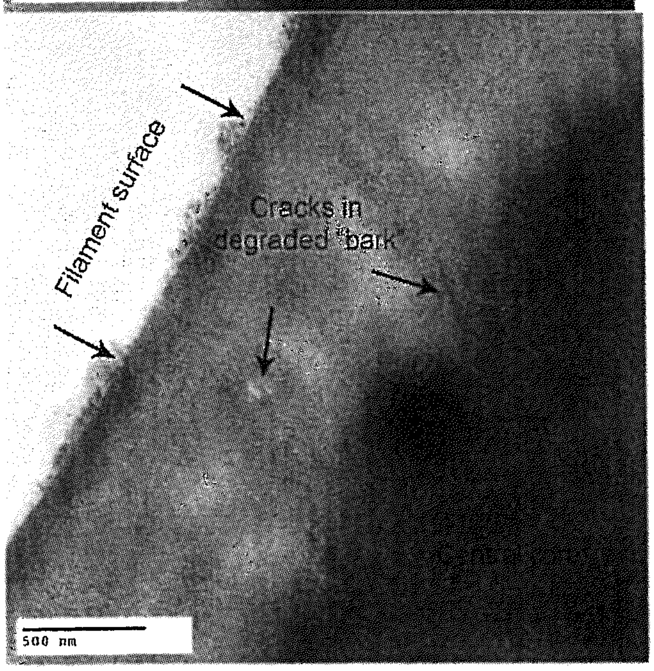


Figure 27. Another area to show the difference between the outer "bark" and the core of the filament. Note the grain and microcracks as well as larger cracks. The "bark" is not separated, however the interface shows higher density and the larger cracks change direction at the interface.


500 nm


Filament surface
Cracks in degraded "bark"
500 nm

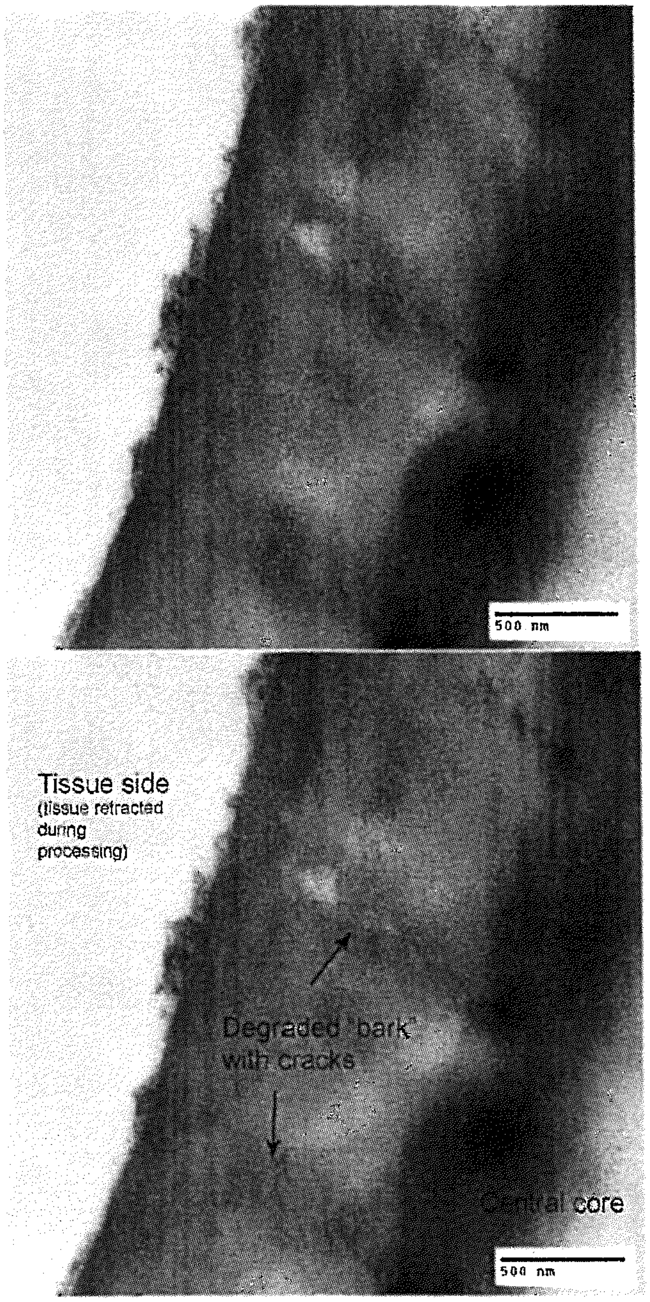
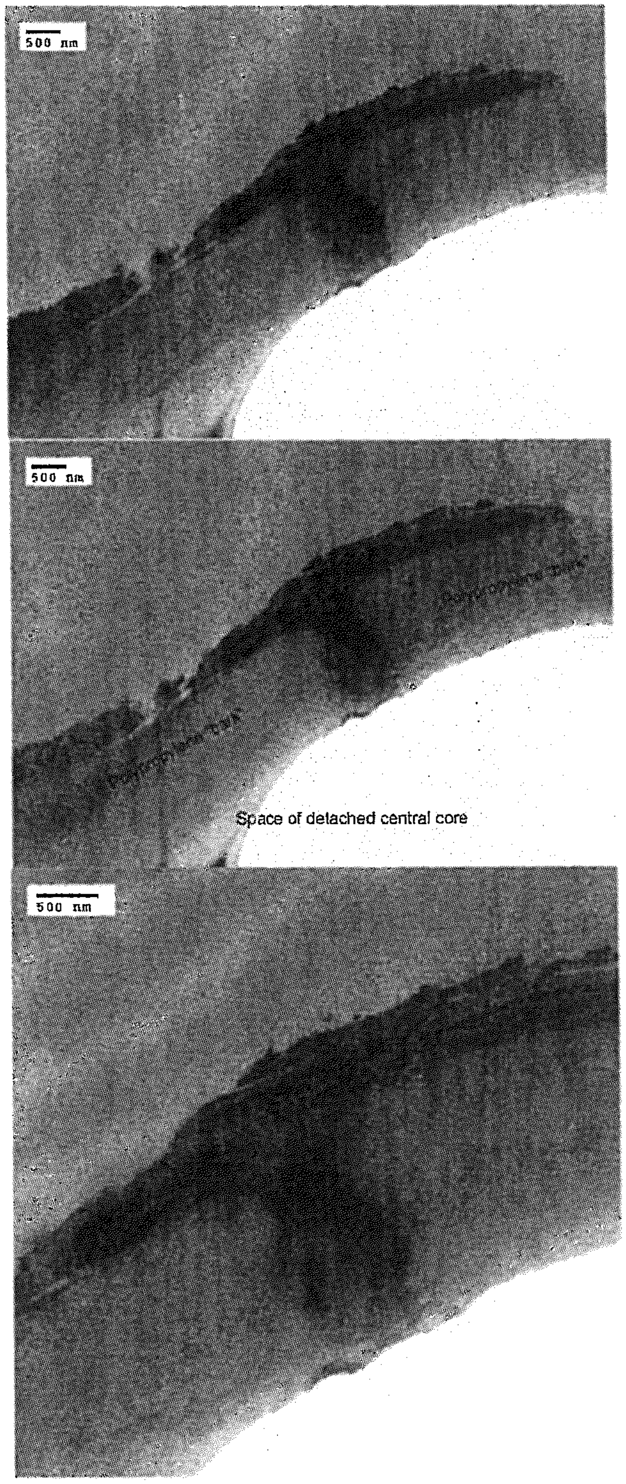
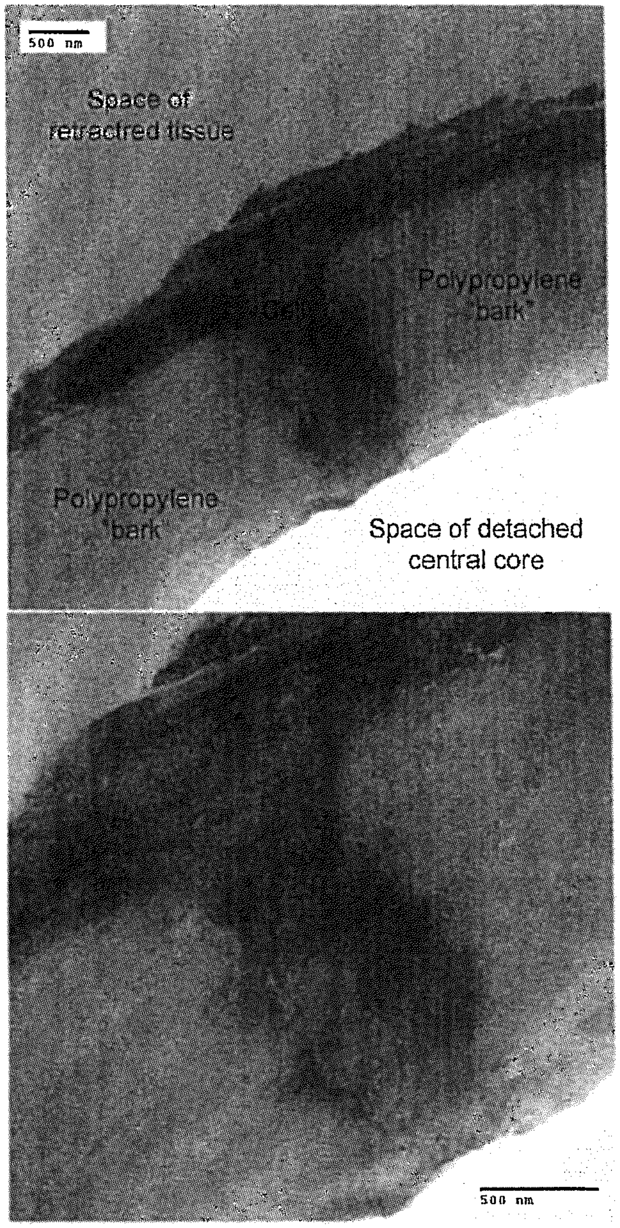
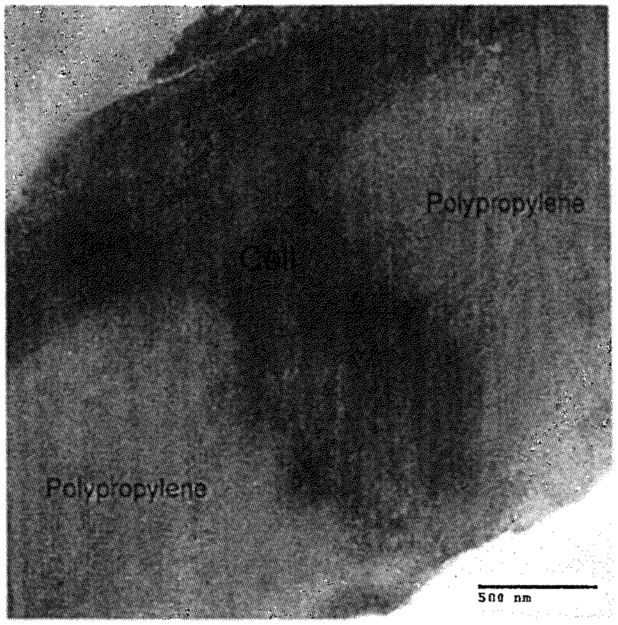
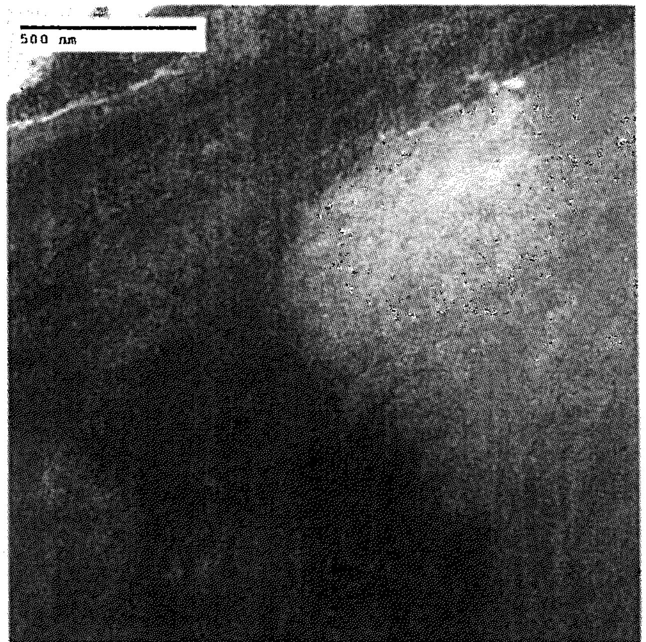


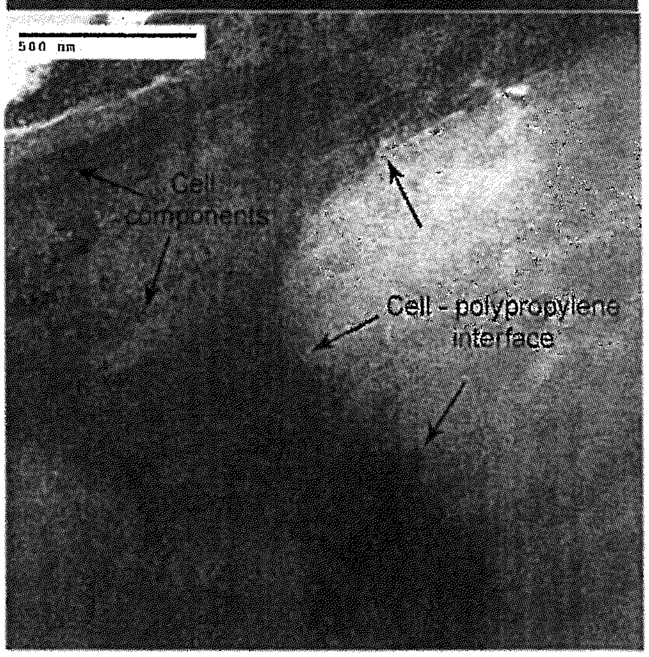
Figure 28. Two more areas of the outer "bark". The outer "bark" showed continuous cracking, where the cracks stopped at the "bark"-core interface.


500 nm
500 nm
Space of detached central core
500 nm


500 nm
Space of retracted tissue
Cell
Polypropylene "bark"
Polypropylene "bark"
Space of detached central core
500 nm


Polypropylene
Cell
Polypropylene
500 nm


500 nm


500 nm
Cell components
Cell - polypropylene interface

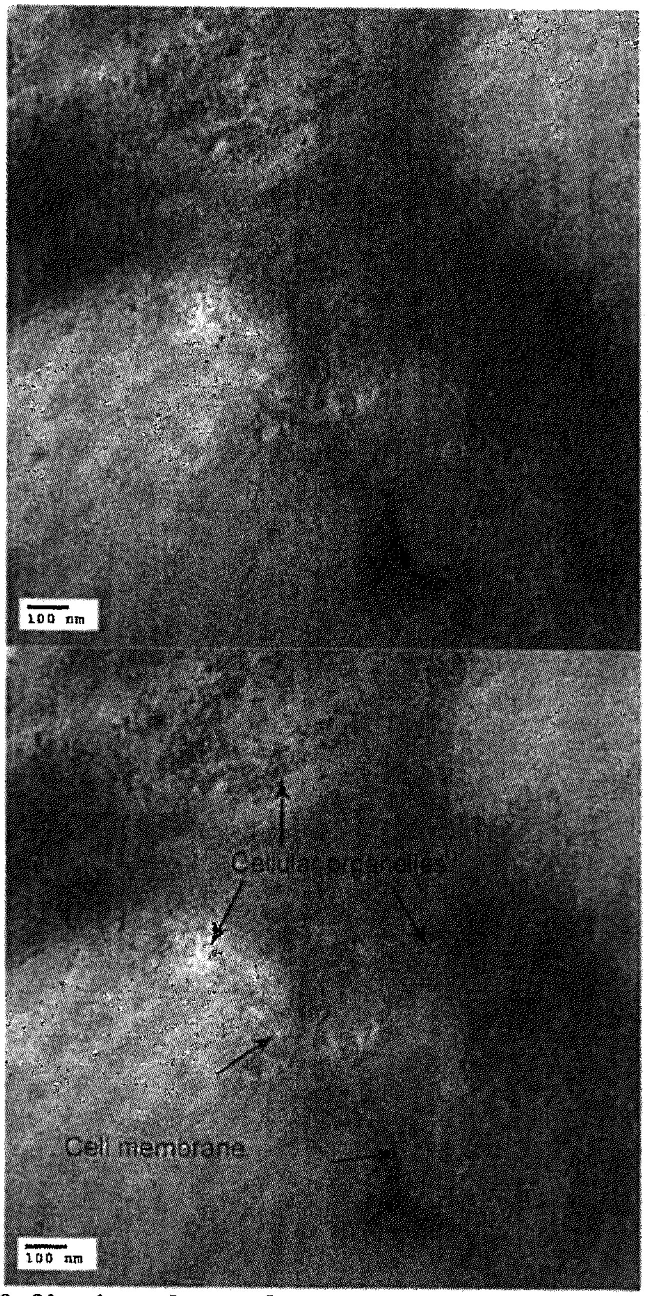


Figure 29. A proof of in-vivo polypropylene degradation, human cell wedged in a "bark" crack

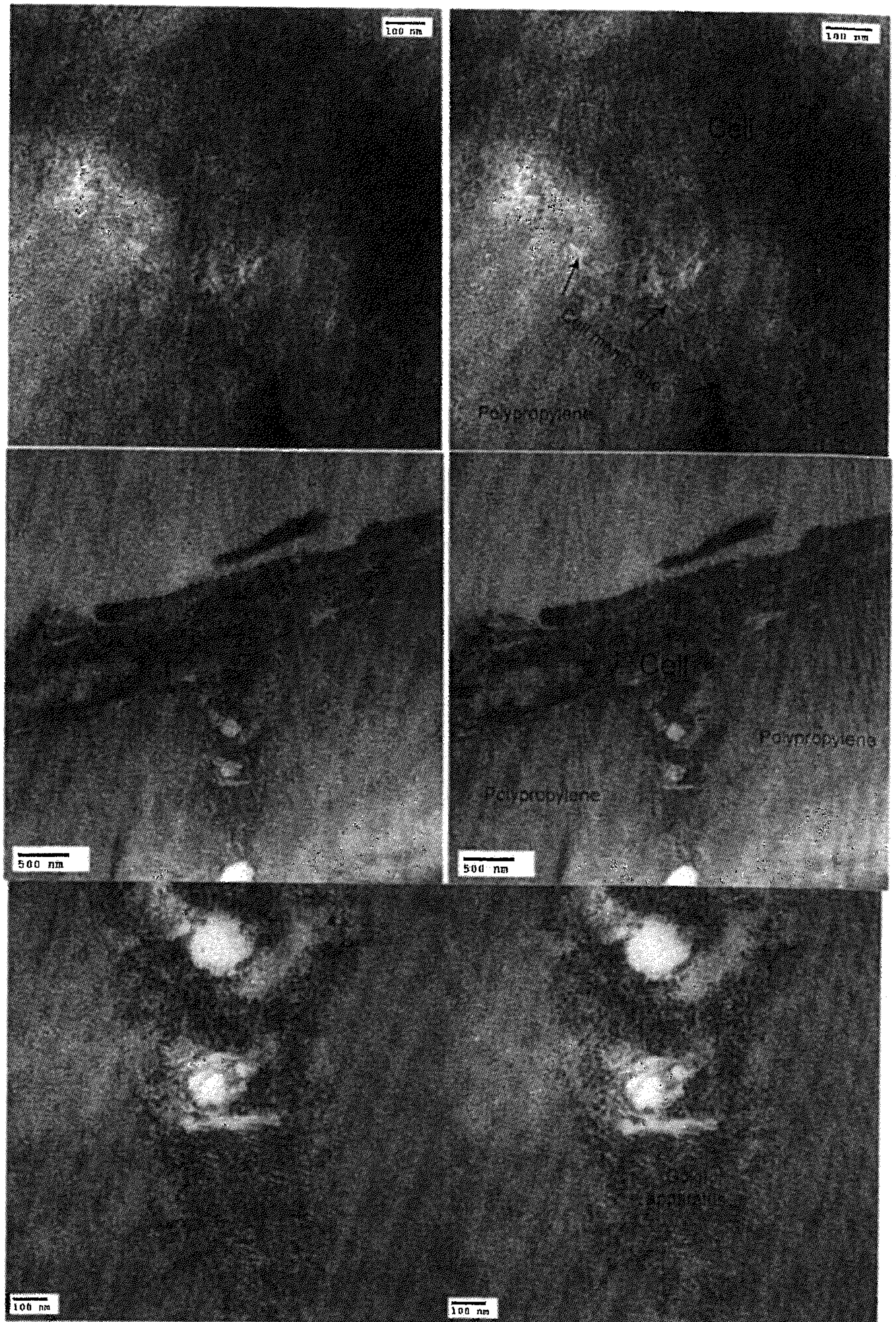


Figure 30. Another cell found wedged in a crack

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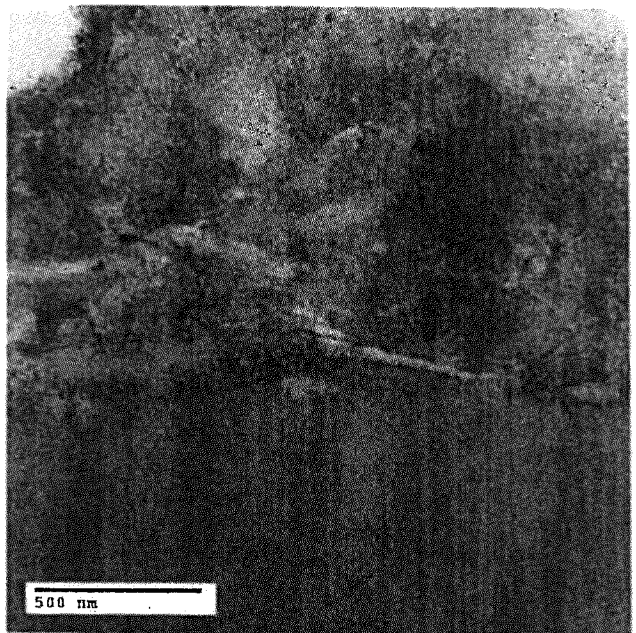
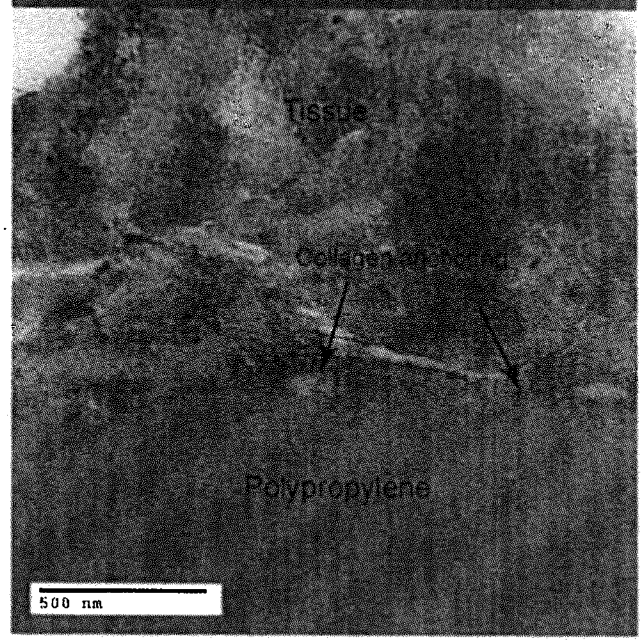

500 nm


Tissue
Collagen anchoring
Polypropylene
500 nm

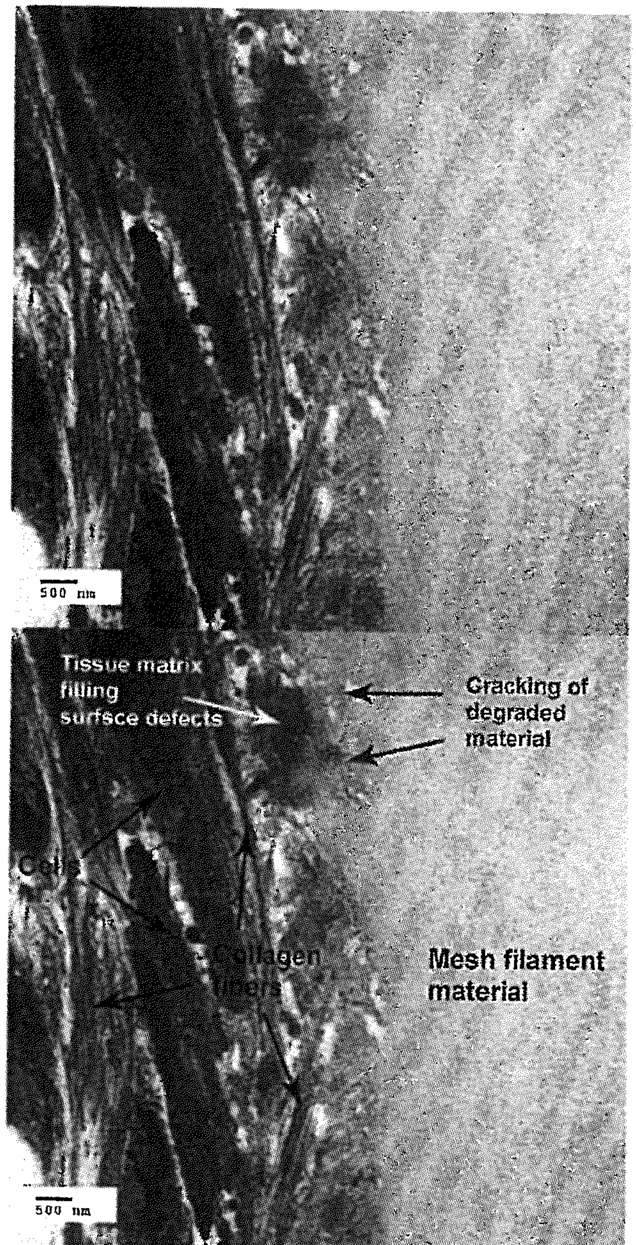


Figure 31. Tissue anchoring to the degraded surface
The interface between a mesh filament and human tissue is shown in photographs. The degraded material has cracks and irregularities. The tissue matrix fills the defects and there is anchoring of collagen to the degraded surface. These findings explain the adherence of the degraded "bark" to the tissue.

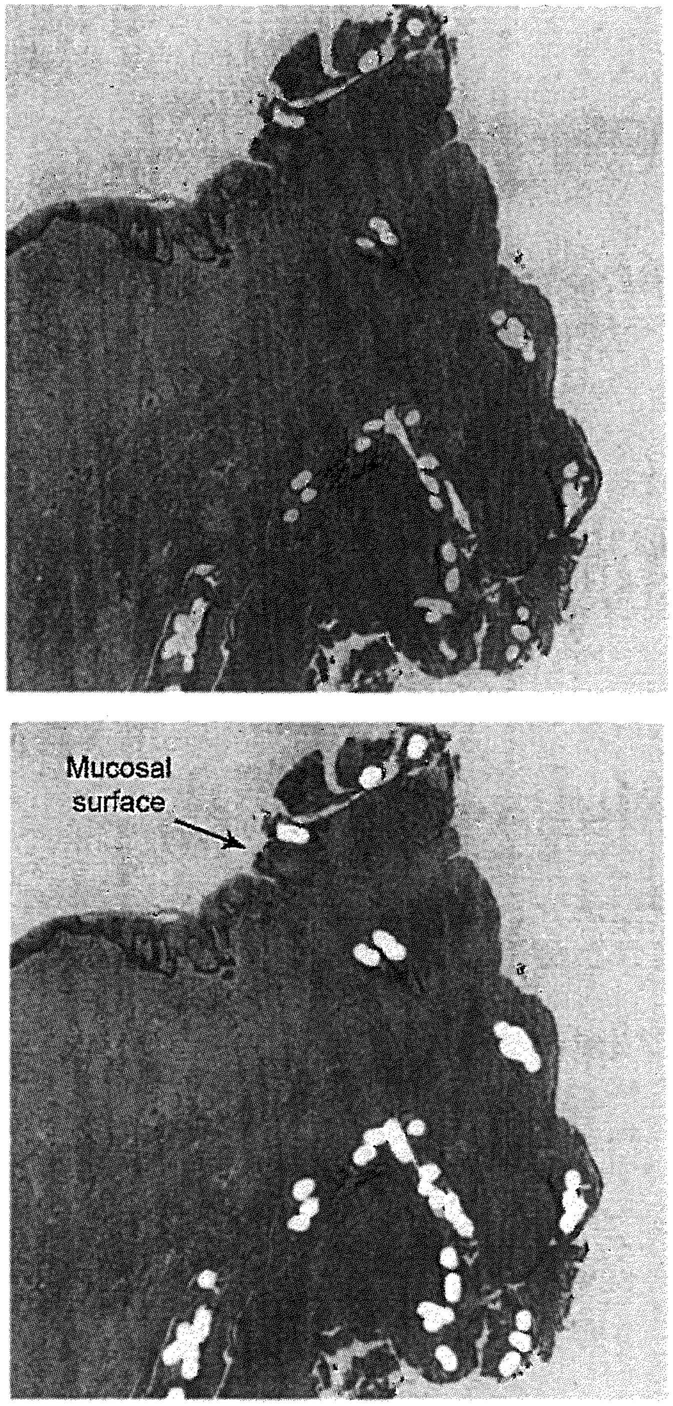


Figure 32. Mesh transmigration through the mucosal surface
The deformed end of the mesh migrated and penetrated the mucosal surface.

Dated this 05 day of December, 2013.

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